The False Claims Act – 2017 Mid-Year Update: Drug and Device Industries

August 2, 2017

Today's Panelists

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Marian Lee is a partner in the Washington, D.C. office. She provides FDA regulatory and compliance counseling to life science and health care companies. Ms. Lee has significant experience advising clients on FDA regulatory strategy, risk management, and enforcement actions.

John Partridge is a partner in the Denver office. He focuses on white collar defense, internal investigations, regulatory inquiries, corporate compliance programs, and complex commercial litigation. He has particular experience with the FCA and the FCPA, including advising major corporations regarding their compliance programs.

Jonathan Phillips is a senior associate in the Washington, D.C. office, where his practice focuses on FDA and health care compliance, enforcement, and litigation, as well as other government enforcement matters and related litigation. He has substantial experience representing pharmaceutical and medical device clients in investigations by the DOJ, FDA, and HHS OIG. Previously, he served as a Trial Attorney in DOJ's Civil Division, Fraud Section, where he investigated and prosecuted allegations of fraud under the FCA and related statutes.

Agenda

- FCA Overview
- FCA Enforcement Developments – General
- Recent FCA Enforcement: Drugs and Devices
    - FDCA & Implied Certification
    - Anti-Kickback Statute
    - Off-Label Promotion
- Questions

FCA Overview

The False Claims Act (FCA)

- The FCA, 31 U.S.C. §§ 3729-3733, is the federal government's **primary weapon to redress fraud** against government agencies and programs.
- The FCA provides for recovery of **civil penalties** and **treble damages** from any person who knowingly submits or causes the submission of false or fraudulent claims to the United States for money or property.
- Under the FCA, the Attorney General, through DOJ attorneys, investigates and pursues FCA cases.
- DOJ is devoting more and more resources to pursuing FCA cases—and considering whether *qui tam* cases merit parallel criminal investigations.

"It seems quite clear that the objective of Congress was broadly ***to protect the funds and property of the Government from fraudulent claims*** …."

Rainwater v. United States, 356 U.S. 590 (1958)

FCA – Key Provisions

31 U.S.C. § 3729(a)(1)	Statutory Prohibition	Summary
(A)	Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval	False/Fraudulent Claim
(B)	Knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim	False Record/Statement
(C)	Knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government	"Reverse" False Claim
(G)	Conspires to violate a liability provision of the FCA	Conspiracy

FCA – Scienter

- "Knowingly" requires scienter and is defined as:
  - Actual knowledge,
  - Deliberate ignorance, or
  - Reckless disregard.
- Negligence is not actionable.
- Specific intent to defraud is not required.

FCA – Overview of Key FCA Theories

Factual Falsity

- False billing (e.g., services not provided)
- Overbilling (e.g., upcoding)

Legal Falsity

- Express certification of compliance with legal requirements
- Submission of claim with representations rendered misleading as to goods / services provided

Promissory Fraud / Fraud in the Inducement

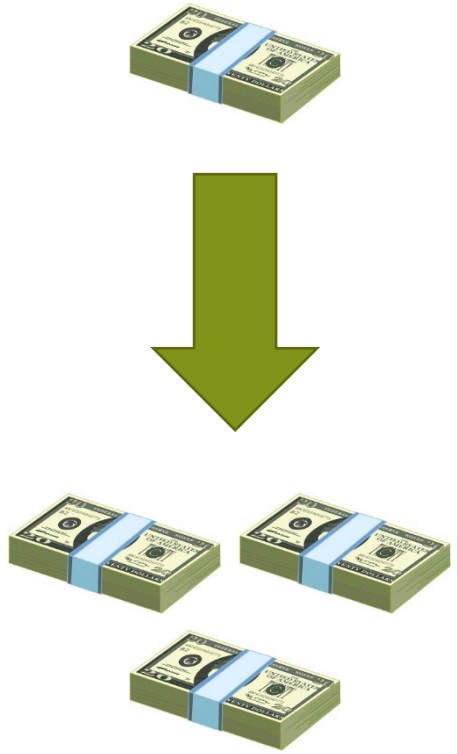
- Obtaining a contract through false statements or fraudulent conduct
- *U.S. ex rel. Marcus v. Hess*, 317 U.S. 537 (1943) (claims by contractors who colluded on bids)

Reverse False Claims

- Improper avoidance of obligation to pay money to the government
- Retention of government overpayment

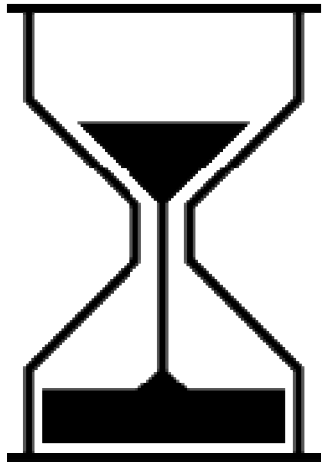
FCA – Damages and Penalties

- **Simple Damages Calculation**
  - Treble damages are traditionally calculated by multiplying the government's loss by three (e.g., if defendant charged government $100 for goods not received, damages would be $300).
- **Complex, Contested Damages Calculation**
  - Calculations are more complicated (and less certain) when the government receives goods or services it considers deficient or when there is a "false certification" or "promissory fraud."
- **Civil Per Claim Penalty**
  - Previously $5,500 to $11,000
  - Nearly doubled effective August 1, 2016
  - 2017 inflation adjustment increased to range of $10,957 to $21,563 per violation



FCA – Statute of Limitations

- The statute of limitations is:
  - 6 years from the date of violation *or*
  - 3 years from when facts material to the violation are known or reasonably should have been known to the government
- ***But*** not more than 10 years from the violation



FCA – *Qui Tam* Provisions

- ***Qui Tam* Provisions**
  - Enable so-called "relators" to bring cases in the government's name and recover **as much as 30%** of favorable judgment or recovery
  - Allow government to intervene
    - An increasing number of whistleblower cases are pursued **without government intervention** (but often with government statement of interest)
  - DOJ has virtually unlimited dismissal authority—but seldom uses it

"In short, sir, I have based the [*qui tam* provision] upon the old-fashioned idea of holding out a temptation and '**setting a rogue to catch a rogue**,' which is the safest and most expeditious way I have ever discovered of bringing rogues to justice."

Statement of Senator Howard, Cong. Globe, 37th Cong. 955-56 (1863)

- **FCA Whistleblower Protections (31 U.S.C. § 3730(h))**
  - Protects employees and others (e.g., contract workers)
  - Relief may include double back pay and interest on back pay; reinstatement (at seniority level); and/or costs and attorneys' fees

FCA – Public Disclosure and First-to-File Bars

- A relator's *qui tam* complaint cannot be "substantially the same" as allegations or transactions publicly disclosed in certain enumerated sources such as public hearings, government audits or reports, or the news media.

  - *Original source" exception*: A relator may proceed on publicly disclosed allegations if he is an "original source" of the allegations, meaning he ***voluntarily disclosed*** them before filing and has knowledge that is "***independent of and materially adds to***" the public disclosures

  - *2010 Amendments*: The public disclosure provisions were amended to the current language by PPACA in 2010; previously, the bar contained slight differences in the public disclosure and original source provisions

- The first-to-file bar provides that, when a *qui tam* action is "***pending***," "***no person*** other than the Government ***may intervene or bring a related action based on the [same] facts***"

Recent Legal Development: Public Disclosure Bar

Amphastar Pharmaceuticals Inc. v. Aventis Pharma SA, 856 F.3d 696 (9th Cir. 2017)

- Affirmed district court dismissal of generic pharmaceutical company's FCA allegations that defendant overcharged the government after fraudulently obtaining a patent on one of its drugs
- Court found that the allegations were publicly disclosed during discovery in its own earlier patent litigation with defendant
  - Although government reimbursement of the drug was not publicly disclosed in that suit, that reimbursement was "***an obvious inference based on the publicly disclosed allegations***"
- Relator also was not an "original source" under the pre-amendment version of the bar because it developed the allegations through the discovery process
  - Relator admitted this fact in its required disclosures to DOJ

Recent Legal Developments: First-to-File Bar

***U.S. ex rel. Shea v. Cellco Partnership, Inc.*, No. 15-7135**
(D.C. Cir. July 25, 2017)

***U.S. ex rel. Carter v. Halliburton Co.*, No. 16-1262**
(4th Cir. July 31, 2017)

- Both courts addressed the question of whether a violation of the FCA's first-to-file provision requires dismissal of the action or, rather, can be cured by an amendment to the complaint
- Both held that the first-to-file provision ***requires dismissal of the second-filed action***, rejecting the argument that amending the second-filed complaint cures the violation of the first-to-file provision

Government Players

DOJ

DOJ is devoting more and more resources to pursuing FCA cases—and considering whether *qui tam* cases merit criminal investigation.

State Attorneys General

State AGs are increasingly conducting investigations and pursuing claims under state False Claims Acts.

Cooperation

Inspectors General

U.S. Department of Health and Human Services: Office of Inspector General

FCA – The Yates Memo

2015 Yates memo set forth 6 priorities for civil and criminal investigations by DOJ, which include FCA investigations:

1. Corporations must provide all relevant facts relating to the individuals responsible for the misconduct in order to qualify for cooperation credit
2. Focus on individuals from the inception of corporate investigation
3. Close coordination between DOJ criminal and civil attorneys
4. DOJ will not release culpable individuals from civil or criminal liability when resolving a matter (absent extraordinary circumstances or DOJ policy)
5. Resolution with corporation should not occur without clear plan to resolve related individual cases
6. Civil attorneys should focus on individuals and evaluate whether to bring suit against individual based on consideration beyond individual's ability to pay

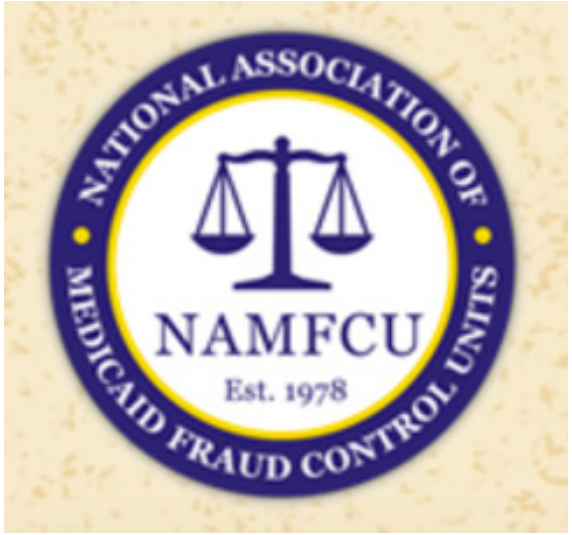
Federal Legislative/Regulatory Developments

- **Health Care Reform**
  - Patient Protection and Affordable Care Act changed key provisions of FCA, including public disclosure bar
  - House and Senate bills left these changes in place
  - Changes to FCA are possible depending on continuance and outcome of repeal efforts

- **Per Claim Penalties**
  - In October 2015, Congress passed legislation requiring agencies to increase FCA penalties to account for inflation
  - On February 3, 2017, the DOJ issued a final rule increasing the per violation FCA penalty range to $10,957 to $21,563 compared to the pre-2016 range of $5500 to $11k

State Developments

- **State Per Claim Penalties**
  - States are amending their false claims acts to match federal per claim penalties
  - States have until December 31, 2018 to make amendments
  - States that do not amend their false claims acts to comply may be deemed less effective than the federal FCA and lose increased share of Medicaid recoveries



FCA Enforcement Developments

By the Numbers: 2016

$4.7 billion

Civil Settlements and Judgments Under the FCA

800

New FCA Cases Filed

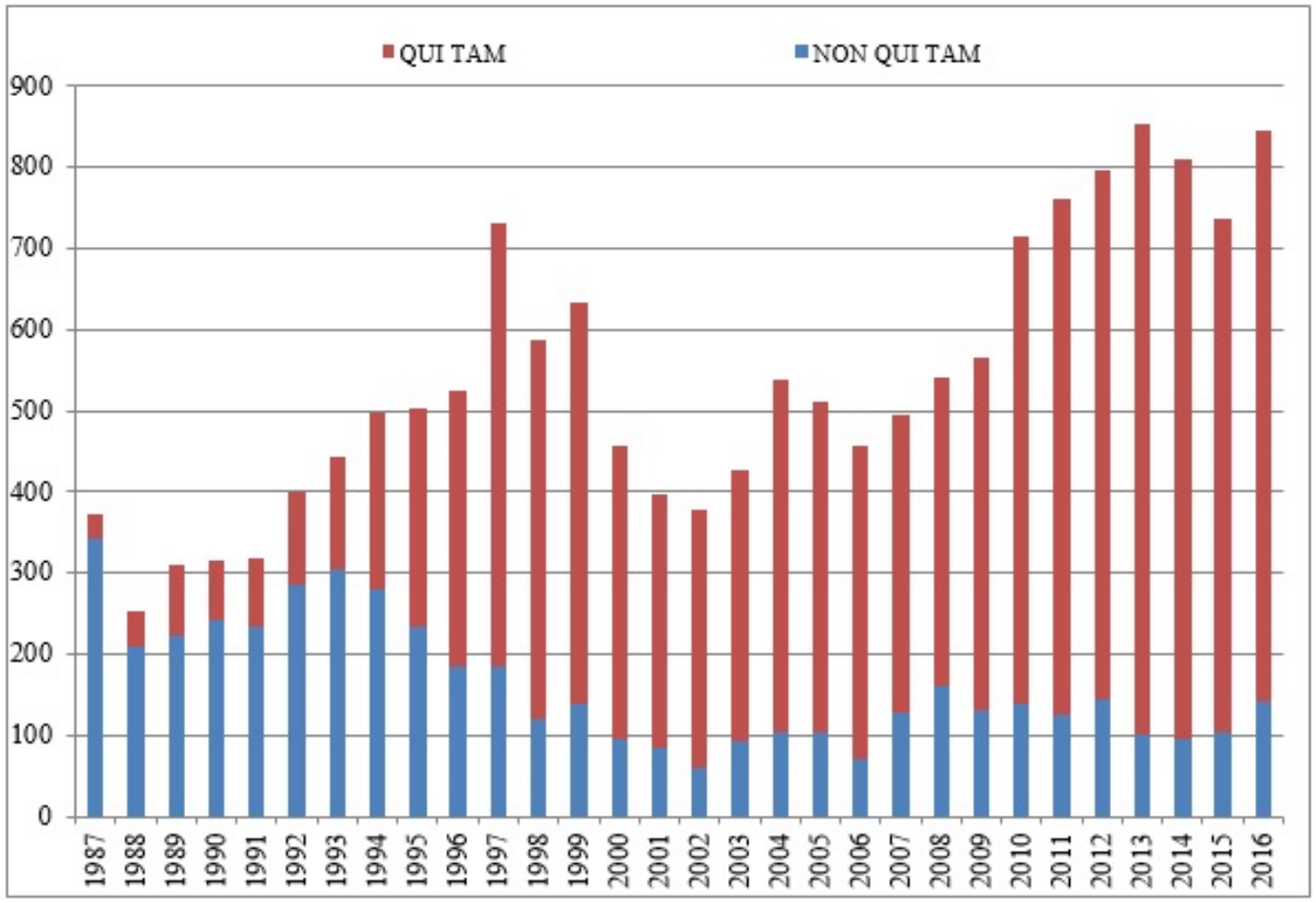
83 percent

Percentage of New FCA Cases Initiated by a Whistleblower

98 percent

Percentage of Overall Federal Recovery from Cases in which the Government Intervened

Number of New FCA Suits (1987-2016)

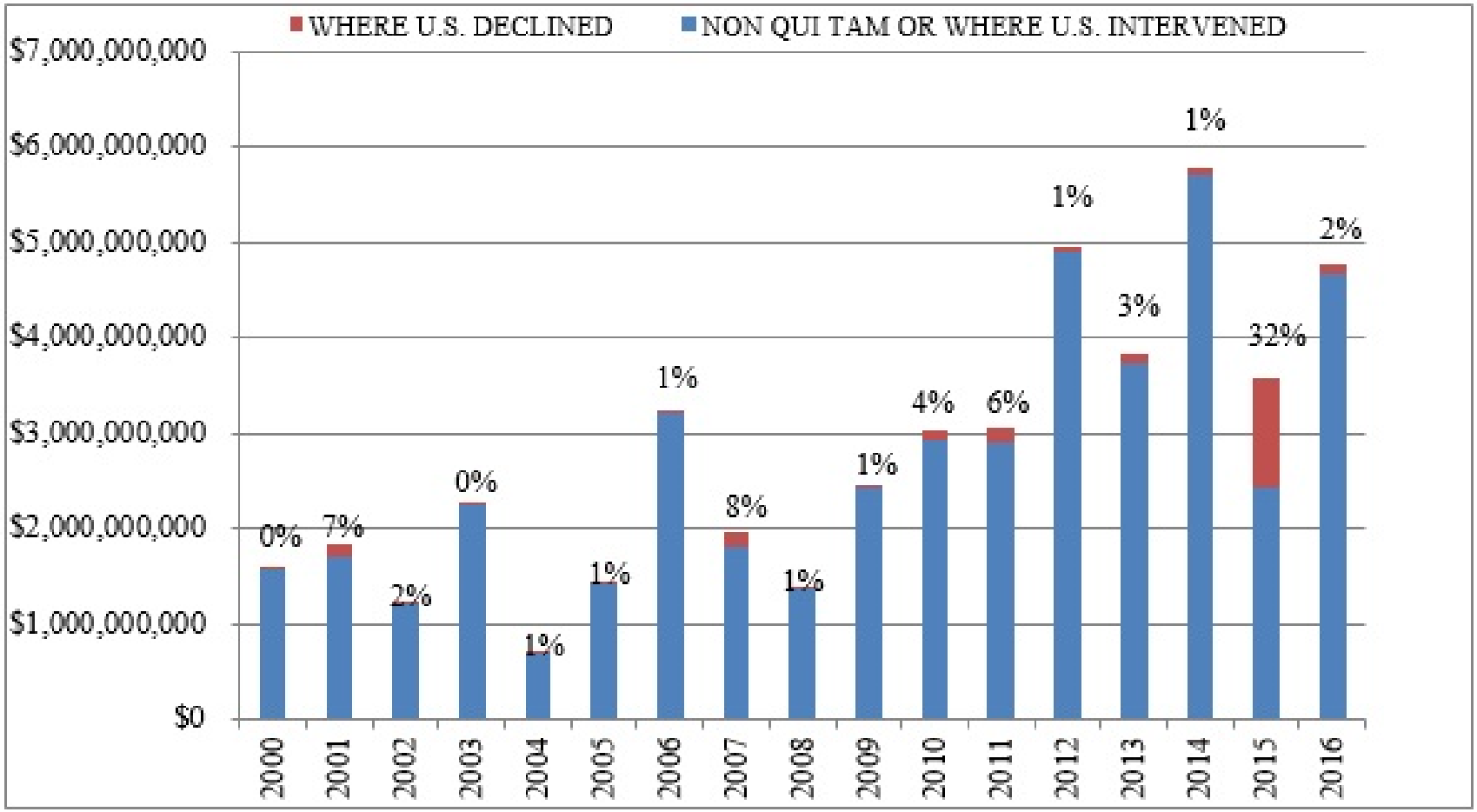


Source: DOJ "Fraud Statistics – Overview" (Dec. 13, 2016)

570 new cases in 2016 related to government health program funds:

- 501 *qui tam* cases
- 69 non-*qui tam* cases

Declined Cases in FCA Settlements / Judgments



Source: DOJ "Fraud Statistics – Overview" (Dec. 13, 2016)

Recent Statements from the New Administration

"We cannot afford to lose a single dollar to corruption, and you can be sure that if I am confirmed, I will make it a high priority of the department to root out and prosecute fraud in federal programs and to recover monies lost due to fraud or ***false claims***."

– Attorney General Jeff Sessions III
(Senate Judiciary Committee Hearing on Nomination of Sen. Jeff Sessions to be Attorney General (Jan. 10, 2017))

"We certainly will continue to enforce [the FCA]" and the DOJ will ensure that "whistleblowers receive any protection they are entitled to by law or regulation."

– Deputy Attorney General Rod Rosenstein
(Senate Judiciary Committee Hearing on Nominations of Rod Rosenstein (Mar. 7, 2017))

Recent Statements from the New Administration

"Nobody supports care being billed for [w]hat isn't needed or . . . hasn't been provided. And [the FCA] is one of those areas that I think we need to be ***very, very focused***. I'm . . . certain that there are some bad actors out there."

– Secretary Tom Price, Department of Health and Human Services
(Senate Finance Committee Hearing on Nomination of Rep. Price to be HHS Secretary (Jan. 24, 2017))

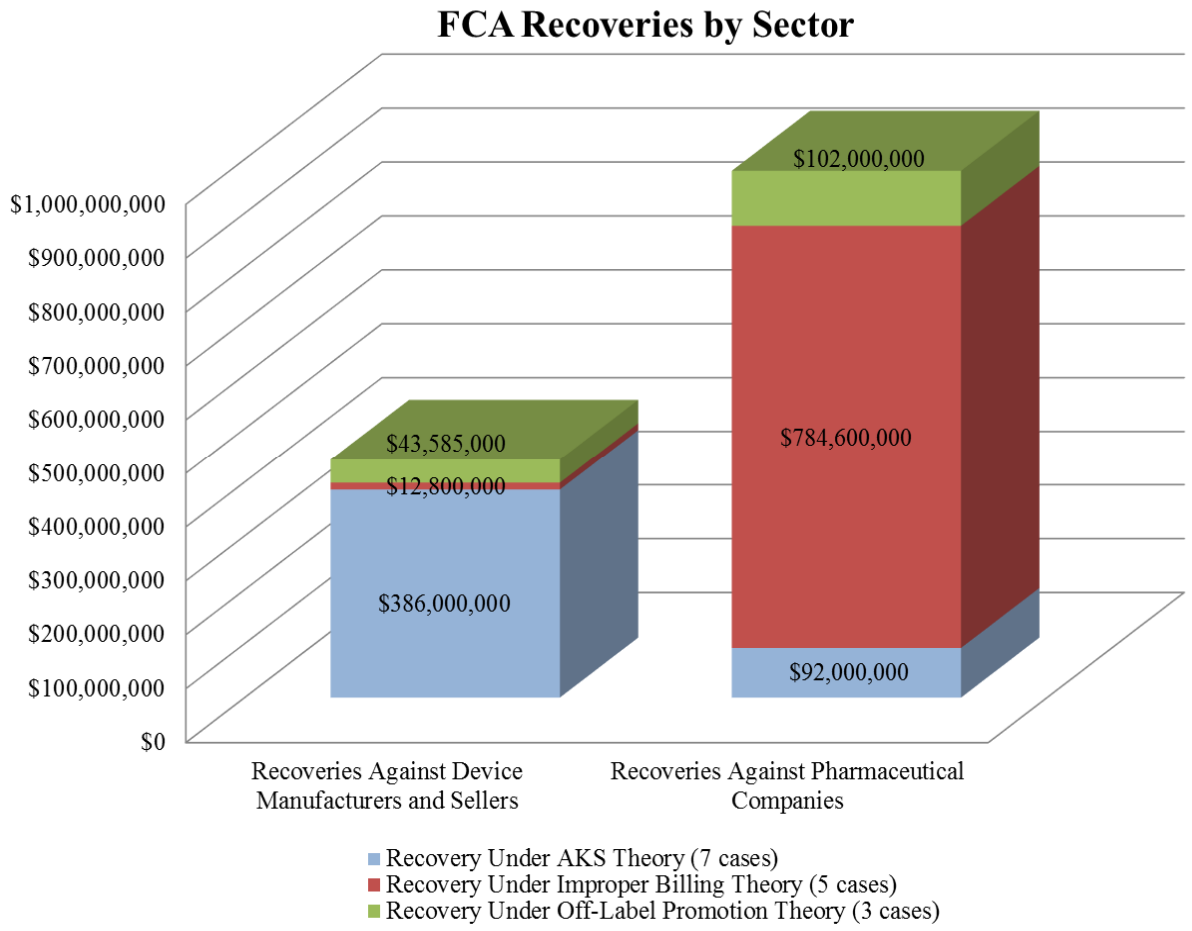
Recent FCA Enforcement: Drugs and Devices

Recent Case Law Developments – Key Legal Theories

- FCA allegations against drug and device companies typically are based on one (or more) of the following legal theories:

1. **Anti-Kickback Statute:** Payment of remuneration to providers in a position to prescribe the company's drug or device violates the AKS and, in turn, the FCA
2. **Off-Label Promotion:** By promoting a drug or device for an off-label use, the company (a) causes the target physicians to submit false claims for reimbursement of a noncompensable use of the drug, and/or (b) engages in a fraudulent course of conduct that can make resulting claims for reimbursement by prescribing physicians fraudulent claims
3. **Violations of the Federal Food, Drug & Cosmetic Act (FDCA):** Allegations that misbranding, adulteration, or pre- or post-approval regulatory violations make claims for reimbursement of associated drugs "false" because (a) the products are tainted by the violative conduct, or (b) there is an "implied certification" of compliance with material regulations when claims for payment of the drugs are submitted
4. **Price Reporting Violations:** Allegations that the company did not report accurate product price information, such as best price, under government program (e.g. Medicaid rebate agreement) requirements

2016 FCA Recoveries – Pharmaceutical and Medical Device



Over **$1.4 billion** in recoveries from drug and device companies in CY2016:

- AKS: $478 million
- Off-label: $145.5 million
- Price reporting and other allegations: $797.4 million

Mid-Year Check-In: July 2017

$1.3 billion

FCA recoveries from settlements in the first half of 2017

$370 million

Judgments from FCA cases in the first half of 2017

8th

DOJ remains on pace for 8th consecutive year exceeding $3 billion in total FCA recoveries

2017 FCA Recoveries to Date: Drug and Device

- **$699 million** in recoveries from drug and device manufacturers year-to-date:
  - Anti-Kickback Statute (2 cases): $363 million
  - Off-label promotion (1 case): $280 million
  - Gov't program requirements (5 cases): $54 million
  - FDCA / cGMP (1 case): $2 million

GIBSON DUNN

Recent FCA Enforcement: FDCA & Implied Certification

GIBSON DUNN

Universal Health Services, Inc. v. U.S. ex rel. Escobar

136 S. Ct. 1989 (2016)

- Relator brought FCA suit against leading nation-wide provider of mental health services, alleging that hospital provided inadequate care to a teenage patient by using personnel to deliver counseling services who did not meet state regulations governing staffing qualifications.

- The Court held that the implied certification theory can provide a basis for FCA liability "at least in certain circumstances":

1. "the claim does not merely request payment, but also makes ***specific representations about the goods or services provided***," and
2. "the defendant's ***failure to disclose noncompliance with material statutory, regulatory, or contractual requirements*** makes those representations misleading half-truths."

Escobar First Condition: Specific Representations

- Implied certification can be a basis for liability "at least" where two conditions are satisfied. The first condition is that "the claim does not merely request payment, but also makes specific representations about the goods or services provided."
  - *Escobar:* UHS submitted claims with payment codes that corresponded to specific counseling services and used NPI numbers that corresponded to specific job titles

Escobar Second Condition: Materiality

- Implied certification can be policed through the FCA's "materiality" and "scienter" requirements
  - Materiality "look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation."
  - Violation is "material" if:
    - "A reasonable man would attach importance to [the mispresented information] in determining his choice of action in the transaction"; or,
    - "the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter 'in determining his choice of action,' even though a reasonable person would not."

Escobar Second Condition: Materiality

- Court holds that "materiality cannot rest on a single fact or occurrence as always determinative," but gives the following guidance for evaluating materiality:
  - Government's right to refuse payment if aware of the violation is insufficient, by itself, to demonstrate materiality
  - Noncompliance cannot be minor or insubstantial
  - Proof can include, but is not limited to, "evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases base don noncompliance with the particular statutory, regulatory or contractual requirement"
  - Government's payment of "particular claim," or practice of paying "particular type of claims," with "actual knowledge" of violation of certain requirements, is "strong evidence" that those requirements are not material

What does *Escobar* mean for drug and device manufacturers?

- Implied certification and "specific representations"
  - Manufacturers themselves are not making representations to the government in most cases
  - Provider claims typically make true statements about the drug being prescribed and the patient's condition
- Materiality
  - Key question: is an FDCA violation, or a misrepresentation during the approval process, "material" to government payment for the drug at issue?

Post-*Escobar*: Specific Representations

Some courts applying *Escobar* have appeared to require, without expressly addressing the issue, that *both* conditions, including the presence of a "specific representations," must be satisfied for implied certification

- *U.S. v. Sanford-Brown*, 840 F.3d 445 (7th Cir. 2016) (holding no implied certification liability because relator failed to plead a "specific representation")

- *U.S. ex rel. Kelly v. Serco*, 846 F.3d 325 (9th Cir. 2017) (holding implied certification claim fails and reasoning in part that defendants' claims made no "specific representations" about performance or other false or inaccurate statements)

Post-*Escobar*: Specific Representations

Others courts have expressly refused to require pleading both conditions:

- *U.S. ex rel. Landis v. Tailwind Sports Corp., et al.*, 2017 WL 573470 (D.D.C. Feb. 13, 2017)
  - Court denied defendant's MSJ, stating that, where the claim forms in question make no specific representations, *Escobar* does not apply
  - Instead, under the D.C. Circuit's pre-Escobar law, "all the government must show is that the contractor withheld information about its noncompliance with material contractual requirements"
- *U.S. ex rel. Badr v. Triple Canopy, Inc.*, 857 F.3d 174 (4th Cir. 2017) (holding that express representation of compliance is not required for there to be an actionable "half-truth" under *Escobar*)

Post-*Escobar* Materiality: Impact of Government Intervention

U.S. ex rel. Badr v. Triple Canopy, Inc., 857 F.3d 174 (4th Cir. 2017)

- Reversed dismissal of allegations that defendant violated FCA by falsifying marksmanship scores of guards providing security for facilities in Iraq
- Held that *both* of *Escobar*'s "two conditions" are ***not required*** to allege a valid implied false certification claim
  - Defendant was not required to certify compliance or make a "specific representation" with regard to marksmanship qualifications, but omissions as to those issues fell "squarely within the rule that half-truths [and] can be actionable"
- In analyzing materiality, the Fourth Circuit concluded that evidence that the "Government did not renew its contract for base security with Triple Canopy and ***immediately intervened in the litigation*** . . . are evidence that Triple Canopy's falsehood affected the Government's decision to pay"

Post-*Escobar* Materiality: Impact of Government Intervention

U.S. ex rel. Petratos v. Genentech Inc., 855 F.3d 481 (3d Cir. 2017)

- Affirmed dismissal of allegations that pharmaceutical company failed to disclose data showing certain common and severe side effects, based on a lack of materiality
- The Third Circuit noted that the relator "not only fails to plead that [the government] consistently refuses to pay' claims like those alleged . . . but essentially concedes that [it] would ***consistently reimburse*** these claims with full knowledge of the purported noncompliance."
- In rejecting materiality, the Third Circuit found persuasive that the Government took ***no action*** after relator disclosed the allegations forming the basis of the complaint: "And in those six years, the Department of Justice has taken no action against Genentech and ***declined to intervene*** in this suit."

Post-*Escobar* Materiality: Government Knowledge

Since *Escobar*, a number of other courts have cited "government knowledge" as support for dismissing claims on materiality grounds:

- *City of Chicago v. Purdue Pharma et al.*, 211 F. Supp. 3d 1058 (N.D. Ill. 2016) (dismissing implied certification claims because government continued to pay for opioids even after becoming aware of alleged "deceptive marketing" of the drugs)
- *Serco*, 846 F.3d at 334 (no materiality where government accepted and paid defendant's reports that on their face did not comply with time-charging guidelines)
- *U.S. ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027 (D.C. Cir. 2017) (affirming summary judgment where government investigation of alleged inflated costs did not result in any disallowance and company continued to receive award fees for exceptional performance)

Post-*Escobar* Materiality: Representations to FDA

D'Agostino v. ev3, Inc., 845 F.3d 1 (1st Cir. 2016)

- Affirmed dismissal of FCA fraudulent inducement claims based on various alleged false representations to FDA by device company during product approval process
- Relator argued that FDA approval was a prerequisite to government reimbursement, and thus the alleged misrepresentations were "capable of influencing" payment, thereby being material
- The court disagreed and reasoned, citing *Escobar*, that materiality requires more
  - In particular, the court noted that CMS's continued reimbursement of the product after the allegations were made "casts serious doubt on the materiality of" the alleged misrepresentations

Post-*Escobar* Materiality: Representations to FDA

D'Agostino v. ev3, Inc., 845 F.3d 1 (1st Cir. 2016)

- The court also found the relator had not alleged the requisite causality between the alleged statements and government payment
- The court again noted that causation was defeated by the government's inaction in response to the relator's claim
- Specifically, the FDA had taken no action despite having the option to impose post-approval requirements or to suspend or withdraw the product's approval

Post-*Escobar* Materiality: Representations to FDA

U.S. ex rel. Campie v. Gilead Sci., 2017 WL 2884047 (9th Cir. July 7, 2017)

- Ninth Circuit reversed district court's dismissal of allegations that defendant fraudulently obtained approval for certain drugs by making false statements to FDA about certain manufacturing and quality testing items
- The court appeared to clearly require both of *Escobar*'s "two conditions" by requiring a "specific representation": "To succeed on [an implied certification] claim . . . [the defendant] must not merely request payment, but also make specific representations about the goods or services provided."
- However, the court reasoned the **drugs' proprietary names alone could constitute a false representation**, because the drug names themselves represent FDA approval.

Post-*Escobar* Materiality: Representations to FDA

U.S. ex rel. Campie v. Gilead Sci., 2017 WL 2884047 (9th Cir. July 7, 2017)

- The court also rejected the argument, adopted by the district court, that any false representations were made to FDA, rather than the payor agency, reasoning:
  - The fraud was against the entire HHS, and the same cabinet secretary therefore oversees both FDA and the payor (CMS)
  - The distinction between the agencies does not matter **if the false statement is "integral to [the] causal chain leading to payment**."

Post-*Escobar* Materiality: Representations to FDA

U.S. ex rel. Campie v. Gilead Sci., 2017 WL 2884047 (9th Cir. July 7, 2017)

- Finally, the court also found the other *Escobar* condition—materiality—was established in the pleading:
  - "**FDA approval is the *sine qua non* of federal funding**. . . ."
  - Departing from the First Circuit's analysis in *D'Agostino*, the court rejected the argument that FDA's decision not to withdraw approval, even after becoming aware of the allegedly withheld manufacturing issues, showed a lack of materiality
    - The court noted "there are many reasons the FDA may choose not to withdraw a drug approval", and here FDA did not need to choose it here because the manufacturing issues had passed
- Notably, unlike the context in *Serco*—a motion for summary judgment—the court observed that "the issues raised by the parties here are matters of proof, not legal grounds to dismiss relators' complaint."

Implications of *Campie*

- The Ninth Circuit's decision in *Campie* increases the possibility that FCA plaintiffs will be successful with theories predicated on FDCA regulatory violations.

- Key regulatory areas that could be more exposed to FCA theories include:
  - cGMP/QSR requirements
  - Adverse Event/Medical Device Reporting requirements
  - Drug development/clinical trials representations and requirements

Baxter Healthcare

- In January, Baxter Healthcare agreed to pay $18 million to resolve potential criminal and civil liability relating to allegations that the company sold adulterated sterile IV solutions because it failed to follow cGMP in manufacturing them.
- Of the $18 million settlement, $2.1 million was designated to resolve allegations that the company's cGMP violations made its claims to the Department of Veterans Affairs false claims under the FCA.
- The company also entered a deferred prosecution agreement, which requires a $16 million monetary penalty and implementation of certain compliance provisions, including certifications to the government.

Case Study: Baxter Healthcare (cont'd)

Baxter

"Following current Good Manufacturing Practices is essential to ensure the safety and efficacy of our drugs. . . . Today's settlement shows that the government **will continue to hold companies accountable for failing to fulfill this critically important responsibility**."

Principal Deputy Assistant AG Benjamin C. Mizer, Head of DOJ Civil Division

$18 million global resolution	$2.1 million for FCA claims

Baxter: the FDA Regulatory Workup

- **2012 and 2013 FDA Inspections** of NC facility

- **2013 FDA Warning Letter** - NC and Puerto Rico facilities
  - Repeat observations
  - Lack of sufficient corrective actions to address NC
  - FDA testing of HEPA filters found mold
  - Failure to identify root cause of mold proliferation
  - Failure to investigate and remediate possible mold per cGMP procedures
  - Lack of scientific justification for sampling plans used in environmental monitoring for manufacture of terminally sterilized injectable product
  - Incomplete environmental monitoring records

Baxter: "No Evidence of Product Impact"

DPA Statement of Facts

No Evidence of Product Impact

37. Per the Environmental Monitoring Plans on file with the FDA and incorporated into the FDA-approved new drug applications for the products manufactured at North Cove, there are established limits for how much mold can be present in the air and on surfaces in the fill rooms. During the relevant time frame, Baxter's testing showed no "out of limits" results.

A-13

Baxter: "No Evidence of Product Impact"

DPA Statement of Facts (cont'd)

38. There are also established limits for how much mold can be in the solution before it is sterilized, as the purpose of North Cove's terminal sterilization process is to kill contaminates like mold prior to product release. There were no "out of limits" test results.

39. Mold is destroyed at temperatures below 194°F, whereas North Cove sterilizes all product at 250°F prior to release. Mold cannot survive at that temperature. North Cove conducts post-terminal sterilization endotoxin testing, which was at all relevant times within limits.

40. There was no evidence of impact on the IV solutions manufactured at North Cove from the mold found on the HEPA filters above the Line 11 clean room.

Other cGMP-related Settlements

GlaxoSmithKline / SB Pharmco Puerto Rico	**Ranbaxy USA**
October 2010	May 2013
$750M	$500M
Cidra, Puerto Rico manufacturing facility	Multiple India manufacturing facilities
• Microbial contamination and product mix-ups in distributed products • Failure to conduct timely investigations and adequate corrective actions (e.g., root cause of recurrent microbial contamination and assessment of impact, Paxil split tablet and visual inspection) • Failure to follow internal procedures intended to prevent these issues • FDA Inspectional Observations (2002-2004) • FDA Product Seizure (March 2005) • FDA Consent Decree (April 2005)	• Falsified data and testing results (bioequivalence, stability, dissolution, etc.) submitted in support of FDA drug applications • Failure to submit timely reports with FDA regarding out-of-spec and failed dissolution tests • Distributed drug after failed stability tests and out-of-spec results • FDA Inspectional Observations • FDA Warning Letters • FDA Import Alerts • FDA Application Integrity Policy (2009) • FDA Consent Decrees (2012, subsequently expanded to include more facilities)

Recent FCA Enforcement: Anti-Kickback Statute

The Anti-Kickback Statute (AKS)

- The AKS, 42 U.S.C. § 1320a-7b(b), criminalizes
  - **knowing and willful**
  - **Payment, offer, solicitation, or receipt of remuneration**
  - **to induce patient referrals, reward a referral source, or generate business**
  - involving any item or service payable by **federal health care programs**.

- The AKS covers **those who provide (or offer)** remuneration and **those who receive (or solicit)** remuneration.

- Since PPACA, a "claim that includes items or services resulting from" a violation of the AKS is a false claim for purposes of the FCA. 42 U.S.C. §1320a-7b(g).

The Anti-Kickback Statute (AKS)

- **Remuneration** includes anything of value, such as:
  - Cash, gifts, hospitality
  - Advisory board salaries
  - Compensation for speaking engagements

- **Statutory exceptions** and **regulatory safe harbors** protect certain payment and business practices that could otherwise implicate the AKS from criminal and civil prosecution, including certain:
  - Discounts
  - Payments to bona fide employees
  - Personal services / management contracts
  - Equipment / space rental contracts

- To be protected by a safe harbor, the arrangement must satisfy all of its requirements.

"In some industries, it is acceptable to reward those who refer business to you. However, in the Federal health care programs, paying for referrals is a crime."

- HHS OIG, *A Roadmap for Physicians, Fraud and Abuse Laws*

The Anti-Kickback Statute – Scienter

- **Willful** means "act[ing] with an **evil-meaning mind**, that is to say . . . with **knowledge that [the] conduct [i]s unlawful**."
  - *Bryan v. United States*, 524 U.S. 184 (1998).

- A key element of AKS liability is intent to induce referrals.
  - **"One purpose test":** Some courts have held that if even "**one purpose**" is to induce referrals, reward a referral source, or generate business, the government views the inducement element as satisfied.

Recent Legal Developments: Anti-Kickback Statute "One Purpose Test"

- ***U.S. ex rel. Ruscher v. Omnicare***, 663 Fed. App'x 368 (5th Cir. Oct. 28, 2016)
  - Affirmed award of summary judgment to defendant on allegations that specialty pharmacy paid kickbacks to providers by not collecting Part A debt and offering prompt payment discounts to induce referrals
  - Court recognized "one purpose test," but held "there is no AKS violation, however, where the defendant merely hopes or expects referrals from benefits that were designed wholly for other purposes"
  - Relators did not show that alleged practices were designed to induce referrals

Recent Legal Developments: Anti-Kickback Statute Generalized Promotion

- ***U.S. ex rel. Brown v. Celgene Corp.***, 226 F. Supp. 3d 1032 (C.D. Cal. Dec. 28, 2016)
  - Awarded SJ to defendant on claims of improper speaker programs and payments for product recommendations
  - Speaker program was "unexceptional" because defendant's payments were not excessive compared to its peers
  - "Recommendations" in the AKS was intended to encompass recommendations to specific patients, not "generalized promotion"
    - Court also noted that FDA reviewed the presentations and "there is no evidence that speakers did anything other than convey truthful scientific information about the drugs"

Recent Legal Developments: Anti-Kickback Statute Generalized Promotion (cont'd)

- ***U.S. ex rel. Brown v. Pfizer***, 2017 WL 1344365 (E.D. Pa. Apr. 12, 2017)
  - Denied defendant's motion to dismiss claims of kickbacks to physicians to recommend its anticancer drug for off-label uses through journal articles, speaker programs, and other promotion
  - Rejected defendant's argument that applying the AKS would penalize its "generalized promotion" of the drug because the allegations involved "marketing tactics utilize[ing] deceit and misrepresentations"
  - Also found the defendant failed to establish all seven of the required elements of the personal services safe harbor

Shire Pharmaceuticals

- In January, Shire Pharmaceuticals agreed to pay $350 million to settle allegations that it violated the FCA by paying kickbacks to providers to use or "overuse" its FDA-approved human skin substitute.
- DOJ alleged that company sales reps induced physicians and clinics to use the product with cash and rebates, "lavish" dinners and entertainment, medical supplies, and payments for "purported speaking engagements and bogus case studies"
- The settlement, a record recovery for a kickback case against a device company, resolved six *qui tams* against Shire and a predecessor company
- Three executives who supervised the alleged kickback scheme, and some providers who received kickbacks, were criminally convicted

Case Study: Shire Pharmaceuticals (cont'd)

"This settlement represents the largest False Claims Act recovery by the United States in a kickback case involving a medical device. . . . Kickbacks by suppliers of healthcare goods and services **cast a pall over the integrity of our health care system. Patients deserve the unfettered, independent judgment of their health care professionals**."

Principal Deputy Assistant AG Benjamin C. Mizer, Head of DOJ Civil Division

$350 million resolution	5 Different DOJ components involved

Recent FCA Enforcement: Off-Label Promotion

Recent Legal Developments: Off-Label

Two potential theories of FCA liability have historically been asserted to support allegations based on promotional conduct:

- **Causing false provider claims:** A company "causes" false claims by promoting a provider's off-label use of a drug that is not compensable by government programs

- **Implied certification:** Misbranding violations under the FDCA are actionable based on a theory of implied false certification of compliance with
    - Related theory: off-label promotion is a fraudulent course of conduct that makes resulting claims actionable under the FCA

Recent Legal Developments: Off-Label Rule 9(b) and Particularized Pleading

- ***U.S. ex rel. Booker v. Pfizer***, 847 F.3d 52 (1st Cir. 2017)
  - Affirmed grant of summary judgment to defendant on claims that psychotropic drug was promoted for off-label pediatric use
  - Only evidence proffered by relators was aggregate Medicaid reimbursement data for the alleged off-label use
  - Court applied Rule 9(b) and confirmed circuit law that where relators "offer only aggregate expenditure data by the government for the drug at issue, without identifying specific entities who submitted claims[,] much less times, amounts, and circumstances, their claims fall far short."

Case Study: Celgene Corporation

Celgene Corp.

- In July, Celgene Corp. agreed to pay $280 million to resolve allegations of off-label promotion of multiple myeloma drugs for use in other cancer treatment.
- Relators alleged that the drugs at issue were approved for certain narrow cancer use in 2005, but the defendant began promoting the drugs for a wide variety of cancers as soon as they hit the market.
- Of the total proceeds, $259.3 million will go to the federal government and $20.7 million will go to the states.
- This settlement is one of the largest ever for a declined case.

Case Study: Celgene (*cont'd*)
Motion for Summary Judgment

- ***U.S. ex rel. Brown v. Celgene Corp.***, 226 F. Supp. 3d 1032 (C.D. Cal. 2016)
  - Denied summary judgment for defendant on relators' off-label promotion claims
  - Court applied "substantial factor" test of causation
  - Court cited primarily to evidence of:
    - Defendant's promotional "campaign" before getting a cancer indication;
    - "General effectiveness" of marketing to doctors;
    - General knowledge of the results of marketing activities;
    - Awareness that doctors submitted Medicare claims for off-label use
    - Plans to provide reimbursement assistance to doctors

Recent Legal Developments: Off-Label FDA's Approach

- "Off-label promotion" is **not defined** in the Federal Food, Drug, and Cosmetic Act or any FDA regulations

- FDA has prohibited manufacturer promotion of off-label uses under several overlapping theories --
  - Constitutes false or misleading labeling
  - Misbranding of product with evidence of a "new intended use" for which "adequate directions" are lacking
  - Promotion creates a new unapproved product for which approval is required

Recent Legal Developments: Off-Label Challenges to FDA's Approach

- ***Caronia* (2012):**
  - The government's interpretation of the FDCA "legalizes the outcome — off-label use — but prohibits the free flow of information that would inform that outcome."
  - Complete ban was more extensive than necessary to advance government interest
- **Amarin (2015):**
  - Court's "considered and firm view" was that FDA may not bring a misbranding action based on truthful promotional speech alone
  - Court refused "to marginalize the holding" in *Caronia* "as fact-bound"
  - Speech vs. conduct: First Amendment protects speech
    - Truthful speech could be evidence of intent to promote off-label use when a manufacturer also "paid doctors money or bought them resort vacations"

Recent Legal Developments: Off-Label Challenges to FDA's Approach

- **<u>Pacira preliminary injunction and settlement (2015 / 2016)</u>:**
  - "The United States confirms that EXPAREL has, since October 28, 2011, been approved for 'administration into the surgical site to produce postsurgical analgesia' for use in a variety of surgeries not limited to those studied in its pivotal trials."
  - FDA withdrew prior Warning Letter
- ***<u>Vascular Solutions</u>* (2016):**
  - Jury instructions: "It is also not a crime for a device company or its representatives to give doctors wholly truthful and non-misleading information about the unapproved use of a device."
  - Complete acquittal of company and CEO

Developments in Regulation of Drug and Device Promotion

- **Evolving definition of "intended use"**
  - January 2017 final rule amending the definition of "intended use" to be based on a "totality of evidence" standard and not on whether a manufacturer had "knowledge of facts that would give him notice" that a product would be used for off-label
  - Delayed to March 2018 to allow for further comment

- **21st Century Cures and Health Care Economic Information (HCEI)**
  - Manufacturer communications with payors, formulary committees, and similar entities
  - HCEI must "relate" to approved drug use, be based on competent and reliable scientific evidence, and include conspicuous and prominent statement describing "material differences" between the HCEI and the approved labeling

Developments in Regulation of Drug and Device Promotion

- **Recent FDA Draft Guidances on manufacturer communications**
  - "Medical Product Communications That Are Consistent With the FDA-Required Labeling — Questions and Answers" (January 2017)
  - "Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities – Questions and Answers" (January 2017)

- **Proposed legislation on manufacturer communications**
  - Two House bills would permit proactive dissemination of scientific information or health care economic information in support of investigational/off-label uses

Recent Legal Developments: Off-Label First Amendment Defense

- ***U.S. ex rel. Gohil v. Aventis, Inc.***, 2017 WL 85375 (E.D. Pa. Jan. 10, 2017)
  - Denied defendant's motion for judgment on the pleadings regarding alleged off-label promotion of defendant's cancer drug
  - Defendant argued that judgment should be entered because truthful, nonmisleading promotion of the drug is protected under the First Amendment
  - Court recognized this as a potential defense, but concluded that whether the promotion was actually false and/or misleading, and thus whether the defense is a permissible one, was a question for the jury

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